

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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MEDICAL DIAGNOSTIC :
LABORATORIES, LLC, :
: Plaintiff, : *Civil Action No.:*
v. :
: HORIZON HEALTHCARE SERVICES, :
INC. d/b/a HORIZON BLUE CROSS :
BLUE SHIELD OF NEW JERSEY; :
HORIZON NJ HEALTH, A MEDICAID :
MANAGED CARE ORGANIZATION; :
and HORIZON HEALTHCARE OF NEW :
JERSEY, INC., :
: Defendants. :
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**COMPLAINT AND JURY
TRIAL DEMAND**

Plaintiff, Medical Diagnostic Laboratories, LLC (“MDL”), by and through its undersigned attorneys, Wilentz, Goldman & Spitzer P.A., for its Complaint against Horizon Healthcare Services, Inc., d/b/a Horizon Blue Cross Blue Shield of New Jersey (“Horizon BC/BS”), Horizon NJ Health, a Medicaid Managed Care Organization (“Horizon Medicaid”), and Horizon Healthcare of New Jersey, Inc. (“Horizon Inc.”), alleges on its knowledge and otherwise upon information and belief as follows:

PRELIMINARY STATEMENT

1. This is a lawsuit based on Federal law prohibiting discrimination by Medicaid managed healthcare organizations (such as Horizon Medicaid) against providers (such as MDL)

in Medicaid funded plans, where those providers serve high risk populations or specialize in conditions that require costly treatment, and for damages as a result of that discrimination.

2. MDL was founded in 1997 and is a privately held genetic and infectious disease clinical laboratory located in Hamilton, New Jersey, and certified under the Clinical Laboratory Improvement Amendments, 42 U.S.C. §263(a), and is accredited by the College of American Pathologists. MDL employs approximately 720 people.

3. MDL's high complexity, state-of-the-art automated DNA-based molecular analyses provide vital information to physicians and other healthcare professionals for the diagnosis, evaluation and treatment of viral, bacterial, fungal and parasitic infections.

4. MDL offers a wide range of genetic and infectious disease testing services, and specializes in providing unique, patented and patent-pending laboratory testing services for detecting multiple pathogens associated with sexual transmitted infections ("STI").

5. MDL is the only laboratory in the United States that supplements its STI testing by providing the clinician with antibiotic resistant results, without charging for an additional test.

6. MDL primarily services women's healthcare providers, and services high risk populations of women who are pregnant, or are at risk of being pregnant, and who are being tested for STIs.

7. This case involves the discriminatory decision by Defendants to exclude MDL from Horizon Medicaid, a Medicaid managed care plan, and to deny the high risk population of women covered by the Horizon Medicaid plan who are pregnant or are at risk of being pregnant from the same STI services offered by MDL, and enjoyed by other patients in the broader Horizon BC/BS network.

8. MDL was and remains an in-network provider for the State of New Jersey for the Medicaid program it directly administers.

9. MDL is also an in-network provider for New Jersey Medicaid managed healthcare organizations through Aetna, Better Health, UHC, Americhoice, Amerigroup, and Wellcare.

10. MDL is also an in-network provider for the Horizon BC/BS PPO plans.

11. In other words, if someone is on Medicaid and is insured with Horizon Medicaid, that person does not have access to MDL's unique and proprietary state-of-the-art laboratory STI tests that other Horizon BC/BS insureds have access to, as well as Medicaid patients under the State's plan, or the plans by other commercial carriers.

12. The decision by Defendants to exclude MDL from Horizon Medicaid and to deny these insureds the same service available to all other patients is a violation of Federal law, specifically 42 C.F.R. §438.214(c).

JURISDICTION AND VENUE

13. This Court has original jurisdiction pursuant to 28 U.S.C. 21§1331 and §1337 because the claims arise under an alleged violation of a Federal statute, 14 U.S.C. §1396(u-2).

14. Venue is proper pursuant to 15 U.S.C. §22 because all Defendants transact substantial business in this judicial district.

15. Venue is also proper in this judicial district under 28 §U.S.C. 1391(b) because Defendants are subject to personal jurisdiction in this district, and further because a substantial part of the events giving rise to the claims asserted herein occurred in this district.

PARTIES

16. MDL is a sole member, limited liability company formed under the laws of New Jersey, with its principal place of business in Hamilton, New Jersey and whose sole member is a citizen of New Jersey.

17. Defendant Horizon BC/BS is, upon information and belief, a non-profit organization under the laws of New Jersey, with its principal place of business in Newark, New Jersey.

18. Defendant Horizon Medicaid is, upon information and belief, a Medicaid managed healthcare entity organized for that purpose by other Defendants.

19. Defendant Horizon Inc., is a domestic corporation with its principal place of business in West Trenton, New Jersey.

20. As more particularly described herein, Defendants' conduct occurred and/or affected interstate commerce and MDL's business in New Jersey and at all materials times Defendants were acting by and through authorized agents, servants and/or employees acting within the course and scope of their employment or agency.

BACKGROUND FACTS

21. MDL services physicians, laboratories and hospitals by offering diagnostic testing services through its sales personnel.

22. MDL specializes in providing patented and patent-pending laboratory testing services for detecting multiple pathogens associated with STIs.

23. Healthcare providers who have an account with MDL are able to request diagnostic tests by sending a paper or electronic test requisition, as well as submitting a specimen in MDL's proprietary *OneSwab®* collection device by courier or express mail service. This

proprietary testing process allows for quick and effective treatment of patients, providing test results to the physicians in as little as 24 hours.

24. MDL's unusually quick turnaround time benefits patients and society as a whole by reducing the spread of communicable diseases, protecting the viability of antibiotics, and preventing health threats to pregnant women and their unborn children.

25. MDL has developed its proprietary tests in response to the global alarm over antibiotic resistance, which the Centers for Disease Control and Prevention ("CDC") statement has described as follows: "Because antibiotic resistance occurs as part of a natural process in which bacteria evolve, it can be slowed but not stopped. Therefore, we will always need new antibiotics to keep up with the resistant bacteria as well as **new diagnostic tests to track the development of resistance.**" (emphasis added)¹

26. By way of example, MDL has developed a test that has been issued a patent by the United States Patent and Trademark Office based on its novelty to determine whether a patient has *Neisseria gonorrhoea* and if so, whether the particular strain of disease the patient has is resistant to certain antibiotic drugs. To the best of our knowledge, MDL is the only clinical laboratory in the United States that currently provides such testing.

27. This testing is highly valuable to medical professionals as it ensures their patients are not prescribed drugs that will not actually cure particular strains of gonorrhea their patients might have.

¹ See, <https://www.cdc.gov/drugresistance/about.html>.

28. The test also helps healthcare providers answer the urgent call of the World Health Organization (“WHO”) to control the spread of antimicrobial resistant strains of gonorrhea.²

29. The CDC, along with the WHO, have determined that providing antibiotic susceptibility testing (“AST”) is essential for many pathogens that are notorious for their ability to mutate and become resistant to antibiotic therapy. Not only does performing antibiotic resistance serve a societal need, it is vital to improve individual patient outcomes, reduce the overall burden of antibiotic resistance, and save healthcare dollars.

30. MDL performs its antibiotic resistant testing as a “reflex” test for diseases which are highly mutable and have developed strains that are resistant to many standard antibiotic treatments. A reflex test is a laboratory test performed subsequent to an initially ordered and resulted test. MDL performs reflex testing automatically at no additional charge, using the same patient specimen on which the original test was performed. Reflex testing is an important tool to providing timely and cost-effective quality-of-care to patients.

31. By way of example, MDL provides reflex antibiotic resistant and susceptibility testing for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, Ureaplasma spp. and *Mycoplasma genitalium*.

32. MDL is the only laboratory whose AST services for *Trichomonas vaginalis*, Ureaplasma spp. and *Mycoplasma genitalium* are performed at the time the infection is detected. This allows the physician to prescribe the correct antibiotic and prevent the spread of the infection.

² See, <https://www.cdc.gov/STD/Gonorrhea/arg/default.htm>.

33. The application of DNA-based technology is particularly useful for slow-growing or non-culturable microorganisms and for the detection of point mutations or certain genotypes.

THE FEDERAL REGULATION

34. The Federal Medicaid law provides in relevant part as follows:

Provider selection policies and procedures...must not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment. 42 C.F.R. §438.214(c)

DEFENDANTS HAVE DISCRIMINATED AGAINST MDL

35. As set forth above, MDL services a high risk population, predominately women who are pregnant or who could become pregnant, and who are being tested for STIs.

36. Defendants maintain a network of healthcare providers with whom they have contracts, generally known as "Provider Agreements."

37. When a healthcare provider enters into a Provider Agreement or similar contract with Defendants, the provider becomes what is known in the healthcare insurance business as "in-network."

38. In connection with the execution of Provider Agreements, in-network providers agree to accept contracted rates of services provided to patients with insurance programs administered by Defendants.

39. Upon information and belief, Horizon Medicaid patients are denied access to MDL's testing that is available to Horizon patients covered by a Horizon commercial plan.

40. Before and after Horizon Medicaid was designated as a carrier for the State's Medicaid managed care program, MDL was an in-network provider for the State Medicaid Plan for laboratory services.

41. Horizon Medicaid continues to deny MDL in-network participation, even though, MDL is an in-network provider for the State's Medicaid program, and for the majority of the other commercial lines of New Jersey Medicaid insurance.

42. Upon information and belief, the majority of Medicaid patients in New Jersey who cannot use MDL's unique STI tests are those covered by Horizon Medicaid.

43. A New Jersey resident who is insured by any other PPO Horizon BC/BS healthcare plan will have access as an in-network provider of MDL's testing.

44. Horizon Medicaid is a managed care program that participates with the New Jersey Division of Medical Assistance and Health Services to provide health coverage for certain groups of low to moderate income adults and children.

45. Defendant Horizon Medicaid advertises on its website that "Horizon NJ Health is the leading Medicaid and NJ FamilyCare plan in the State and the only one backed by Horizon Blue Cross/Blue Shield of New Jersey." (emphasis added)

<http://www.Horizonnjhealth.com/why/horizon> (visited October 20, 2017).

46. Horizon Medicaid further states on its website that "everyone deserves quality healthcare – people and their families who qualify for Medicaid deserve to receive the best quality care from their health plan." <http://www.Horizonnjhealth.com/ourplans> (visited October 20, 2017).

47. These representations are false. Defendants have not offered the same quality of healthcare to its Medicaid members as it offers to non-Medicaid members insured by Defendants because if that were the case, Defendants would allow its Medicaid patients access to the same patented and proprietary testing that MDL offers as is available to other Horizon BC/BS insureds.

48. Other laboratories do not and cannot provide the unique, patented and proprietary STI testing laboratory services that MDL offers.

49. There is no legitimate business reason to exclude MDL from Horizon Medicaid, other than the improper purpose to discriminate against MDL and to deny the same unique, proprietary and patent pending testing to high risk Medicaid patients covered by other Horizon BC/BS plans.

50. That conduct is precisely what Federal law prohibits.

51. MDL has made application to Horizon Medicaid to become a participating provider and to accept the Horizon Medicaid in-network reimbursement rates, but Defendants have denied MDL's application.

FIRST COUNT

52. MDL repeats and realleges by reference each preceding paragraph of this Complaint, as if set forth in full herein.

53. Federal law prohibits discrimination in a Medicaid health plan (such as Horizon Medicaid) against any provider (such as MDL) which services high risk populations (such as women who are pregnant or are at-risk of being pregnant), which describes a large segment of MDL's clientele.

54. Defendants have unlawfully excluded MDL from Horizon Medicaid managed care program for no legitimate business purpose since MDL has agreed in its provider agreement application to accept the in-network rates for the Medicaid patients.

55. Many physicians prefer MDL's laboratory services for the reasons set forth herein.

56. MDL has performed laboratory tests for Horizon Medicaid insureds, but has not been paid by Defendants for the services

WHEREFORE, MDL demands judgment against Defendants for damages and for such other relief as the Court deems just and equitable.

JURY DEMAND

Plaintiff herein demands trial by a jury.

BY:


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